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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,290	04/12/2000	Tatsuya Sasakawa	0018-1098-0	6669

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1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/548,290

Applicant(s)

SASAKAWA ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29,30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-30 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/05 has been entered. Further, as requested, the request for reconsideration and declaration under 1.132 filed on 12/13/04 have been considered. Claims 29-30 and 32-37 are pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 29-30 and 32-36 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46, is maintained.

The rejection of claim 37 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46 as applied to claims 29-30, and

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32-36 above, and further in view of Hiroi et al. (1998) *Jpn. J. Pharmacol.*, Vol. 76, 175-183, is maintained.

The applicant has addressed the two rejections presented above together. Applicant's arguments and the declaration of Dr. Sakuma under 37 CFR 1.132 have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant's response discusses the declaratory evidence provided in the Declaration by Dr. Sakuma which seeks to demonstrate that the mice of the claimed invention have unexpected properties not taught or suggested by the combination of Morita et al., Yasue et al., Gad alone or in combination with Hiroi et al. In particular, the response argues that the Declaration provides post-filing evidence from the inventors that the a mouse prepared according to the claimed invention has several "unexpected" properties compared to the closest prior art as represented by mice taught in Hiroi et al., including an enhanced ability to predict the efficacy of steroids in treating atopic dermatitis, and a more rapid establishment of symptoms such that the mice can be used in 2-3 weeks as a model for atopic dermatitis, compared to 4 or more weeks. The declaration itself is based on two post-filing papers by the instant inventors. The first paper, Sasakawa et al. (2000) *Int. Arch. Allergy Immunol.*, Vol. 126, 239-247, discusses the establishment of a mouse model for atopic dermatitis. Sasakawa teaches injecting mite extract into the ear of SPF NC/Nga mice on days 0, 2, 4, 7, 9, 11, 14, and 16, resulting in the development of AD-like skin lesions including erythema, edema, excoriation, and scaling by day 18. The second paper, Sasakawa et al. (2004) *Int. Arch. Allergy Immunol.*, Vol. 133, 55-63, demonstrates that the mouse model prepared as in the first Sasakawa paper can be used to screen

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drugs for the ability in inhibit/treat dermatitis. In particular, the second paper shows that both FK506 and betamethasone valerate, a corticosteroid, have efficacy in treating the symptoms of dermatitis in the Sasakawa mouse model. The declaration compares these results with the nearest closest mouse model, which is the NC/Nga mouse infected with live mites as used in both Morita et al. and Hiroi et al. In a table, the declaration shows that whereas the Sasakawa mouse model predicted that both the steroid and FK506 would be useful in treating atopic dermatitis like symptoms, the Hiroi et al. model was only able to predict the efficacy of FK506. The declaration also points out that because of the time involved in allowing environmental mites to establish infection of the previously SPF NC/Nga mice in the Hiroi method, these mice could not be used as a model until at least 4 weeks, whereas the Sasakawa mice could be used at 2-3 weeks. The applicant concludes that the results described above are “unexpected” over the art and that the combination of Morita et al., Yasue et al., Gad and Hiroi et al. could not lead the skilled artisan to expect that a mouse prepared according to the instant invention would have these properties.

In response, evidence of unexpected properties must be weighed against evidence supporting *prima facie* obviousness in making a final determination of the obviousness of the claimed invention. *In re May*, 574 F.2d. 1082 and MPEP 716.02(c). Further, objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support. *In re Clemens*, 622 F.2d 1029 and MPEP 716.02(d). The mice in the submitted post-filing Sasakawa et al. references were administered multiple injections of mite extract in a single ear over a period of 16 days. While multiple administration of mite extract fall within the scope of the claims as written, the claims are not so limited and read on a single administration of mite extract to the ear of an SPF NC/Nga mouse. Thus, the evidence provided is not commensurate in

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scope with the claims as written. Further, neither of the “unexpected” properties discussed in the declaration and response are recited in the instant claims, nor is it clear that a single administration of mite extract would produce these properties. The claims as written simply recite a mouse model for atopic dermatitis and a method of screening an agent for effectiveness against atopic dermatitis. The rejection of record provides motivation for making a mouse according to the instant claims and further provides a reasonable expectation of success in being able to identify an agent effective in treating atopic dermatitis using this mouse model, see for instance Hiroi which shows that NC/Nga mice exposed to mites develop dermatitis like symptoms which can be treated by FK506(tacrolimus). While the applicant’s results may show that the claimed mice are capable of demonstrating the effectiveness of steroids in treating dermatitis, a result not expected from the teachings of cited references, the claims are not so limited. In regards to the time it takes for the claimed mice to be used as a model to test treatments, it is noted that only claim 37 is directed to methods of screening, the rest of the claims are directed to the mouse itself and methods of making the mouse. Therefore, based on the totality of the evidence of record, the applicant’s newly submitted declaratory evidence is not deemed sufficient to overcome the *prima facie* case for obviousness.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner’s

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supervisor, Ram Shukla, can be reached at (571) 272-0735. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal flourish extending to the right.